PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applic	ation of:)
• •	James Hunter Boone, et al.)
Serial No.	10/656,034) Art Unit:
Filed:	September 5, 2003) Examiner:
Title:	Method for Distinguishing Ulcerative Colitis from Crohn's Disease by Detecting the Presence of Fecal Anti- Neurophil Cytoplasmic Antibodies (ANCA)	Attorney Docket: TLAB.100294 CERTIFICATE OF MAILING 37 C.F.R. 1.8 I hereby certify that this correspondence is being deposited with the U.S. Postal Service, postage prepaid, as First Class
	r	Mail in an envelope addressed to: Mail Stop DD, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: 12/4/03 Date Signature

INFORMATION DISCLOSURE STATEMENT

Mail Stop DD Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In compliance with Applicants duty of disclosure pursuant to 37 C.F.R. Section 1.56, it is requested that this Information Disclosure Statement be entered and that the references listed below and on the enclosed Form PTO-1449 be considered by the Examiner and made of record. Copies of the above-referenced documents are enclosed.

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U.S. PATENT NUMBER	ISSUE DATE	INVENTOR
5,359,038	October 25, 1994	Padron, Eloy
5,932,429	August 3, 1999	Targan, et al.
5,968,741	October 19, 1999	Plevy, et al.
6,218,129	April 17, 2001	Walsh, et al.

OTHER DOCUMENTS (Including Author, Title, Relevant Pages, and Place of Publication, Date)

- R. Barnes, S. Allan, C. Taylor-Robinson, R. Finn, P. Johnson, "Serum Antibodies Reactive with *Saccharomyces cerevisiae* in Inflammatory Bowel Disease: Is IgA Antibody a Marker for Crohn's Disease?" *Int Arch Allergy Appl Immunol* (1990) 92, 9-15.
- C. Faille, D. Mackenzie, J. Michalski, and D. Poulain, "Evaluation of an Enzyme Immunoassay Using Neoglycolipids Constructed from *Candida albicans* Oligomannosides to Define the Specificity of Anti-Mannan Antibodies" *Eur. J. Clin. Microbiol. Infect. Dis.*, (1992) May, 438-446.
- M. Giaffer and C. Holdsworth, "Antibodies to Saccharomyces cerevisiae in patients with Crohn's disease and their possible pathogenic importance" Gut (1992) 33, 1071-1075.
- S. Hanauer, "Inflammatory Bowel Disease" *The New England Journal of Medicine* (1996) 334, 841-848.
- S. Hanauer and G. D'Haens, "Medical Management of Ulcerative Colitis" in Targan and Shanahan Inflammatory Bowel Disease: From Bench to Bedside, *Williams and Wilkens* (1994) 545-561.
- C. Jongeneel, L. Briant, I. Udalova, A. Sevin, S. Nedospasov, and A. Thomsen, "Extensive genetic polymorphism in the human tumor necrosis factor region and relation to extended HLA haplotypes" *Proc. Natl. Acad. Sci. USA* (1991) 88, 9717-9721.
- E. Lindberg, K. Magnusson, C. Tysk, and G. Jarnerot, "Antibody (IgG, IgA, and IgM) to baker's yeast *Saccharomyces cerevisiae*), yeast mannan, gliadin, ovalbumin and betalactoglobulin in monozygotic twins with inflammatory bowel disease" *Gut* (1991) 909-913.
- J. Main, H. McKenzie, G. Yeaman, M. Kerr, D. Robson, C. Pennington, and D. Parratt, "Antibody to Saccharomyces cerevisiae (bakers' yeast) in Crohn's disease" *BMJ* (1988) 297 1105-1106.
- H. McKenzie, J. Main, C. Pennington, and D. Parratt, "Antibody to selected strains of *Saccharomyces cerevisiae* (baker's and brewer's yeast) and *Candida albicans* in Crohn's disease" *Gut* (1990) 31, 537-538.

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- H. McKenzie, D. Parratt, J. Main, and C. Pennington, "Antigenic heterogeneity of strains of *Saccharomyces cerevisiae* and *Candida albicans* recognized by serum antibodies from patients with Crohn's disease" *FEMS Microbiology Immunology* (1992) 89, 219-224.
- H. Yang, J. Rotter, H. Toyoda, C. Landers, D. Tyan, C. McElree, and S. Targan, "Ulcerative Colitis: A Genetically Heterogeneous Disorder Defined by Genetic (HLA Class II) and Subclinical (Antineutrophil Cytoplasmic Antibodies) Markers" *The American Society for Clinical Investigation, Inc.* (1993) 92, 1080-1084.
- C. Young, A. Sonnenberg, and E. Burns, "Lymphocyte Proliferation Response to Baker's Yeast in Crohn's Disease" *Digestion* (1994) 55, 40-43.
- M. Giaffer, A. Clark, C. Holdsworth, "Antibodies against Saccharomyces Cerevisiae (Baker's & Brewer's yeast) in Crohn's Disease" Gastorenterology (1991) 100, No. 5, Part 2.
- G. Barclay, H. McKenzie, J. Pennington, D. Parratt, and C. Pennington, "The Effect of Dietary Yeast on the Activity of Stable Chronic Crohn's Disease" *Scand J Gastroenterol* (1992) 27, 196-200.
- M. Broker, H. Harthus, and R. Barnes, "A murine monoclonal antibody directed against a yeast cell wall glycoprotein antigen of the yeast genus *Saccharomyces*" FEMS Microbiology Letters (1994) 118, 297-304.
- C. Darroch, S. Christmas, and R. Barnes, "In vitro human lymphocyte proliferative responses to a glycoprotein of the yeast Saccharomyces cerevisiae" Immunology Letters (1994) 81, 247-252.
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- N. Oshitani, et al., <u>IgG subclasses of anti Saccharomyces cerevisiae</u> antibody in inflammatory bowel disease; Blackwell Science Ltd., European Journal of Clinical Investigation, Vol. 31, pp. 221-225, 2001.

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FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

EXAMINER INITIAL	PUBLICATION NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS
	WO 99/60403	25 November 1999	PCT	G01N 33/564, 33/569	
	WO 97/39356	23 October 1997	PCT	G01N 33/564	
	WO 98/46997	22 October 1998	PCT	G01N 33/53, C12Q 1/68	
	WO 01/11334 A2	15 February 2001	PCT	G01N	

Respectfully submitted,

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Attorney Docket No. TLAB.100294

PATENT Serial No. 10/656,034

DEC 0 8 2003

PTO-1449 (Modified) Attorney Docket No.: Serial Number: 10/656,034 840244 **U.S. DEPARTMENT OF COMMERCE** TLAB.100294 PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT **BY APPLICANT** Applicant: James Hunter Boone, et al. Method for Distinguishing Ulcerative Filing Date: September 5, 2003 Group: Title: Colitis from Crohn's Disease by Detecting the Presence of Fecal Anti-Neurophil Cytoplasmic Antibodies (ANCA)

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	WO 99/60403	11/25/1999	PCT		G01N 33/564, 33/569	YES	NO	
	WO 97/39356	10/23/1997	PCT		G01N 33/564			
	WO 98/46997	10/22/1998	PCT		G01N 33/53, C12Q 1/68			
	WO 01/11334 A2	02/15/2001	PCT		G01N			
				1				

EXAMINER DATE CONSIDERED

EXAMINER: Initial citation if reference was considered. Draw line through citation if not in conformance to MPEP 609 and not considered. Include copy of this form with next communication to applicant.

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